UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
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15 JUNE 2005

APPROVAL SHEET

Title of Thesis: "Verification of Caregraph® Peak Skin Dose Data Using Radiochromic Film"

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Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
2005		**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Verification of Caregraph® Peak Skin Dose Data Using Radiochromic Film	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **Uniformed Services University of the Health Sciences,F. Edward Hebert School of Medicine,4301 Jones Bridge Road,Bethesda,MD,20814-4799**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES
The original document contains color images.

14. ABSTRACT
see report

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**		**49**	

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ABSTRACT

Title of Thesis: "Verification of Caregraph® Peak Skin Dose Data Using Radiochromic Film"

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Radiation-induced skin injury during fluoroscopically guided interventional procedures has become an important concern and has been documented for interventional neuroradiology and cardiology procedures.[1-4] The risk to any location on the skin increases with the radiation dose to that portion of the skin,[3,5,6] and the maximum dose delivered to any portion of the skin during a procedure (the peak skin dose) determines the risk of injury at that point.[7,8]

Peak skin dose (PSD) may be determined using x-ray film or thermoluminescent dosimeters , but neither provides real-time data. A software program called Caregraph® estimates PSD in real-time based on information from the fluoroscopic unit to which it is linked.

The purpose of this study was to compare the skin dose estimates produced by Caregraph® with the PSD data determined with radiochromic dosimetry film placed against the surface of a tissue-simulating phantom in

configurations simulating actual clinical situations. The radiochromic film was calibrated to include backscatter values at the National Institute of Standards and Technology.

Caregraph® estimated the PSD to within 15% of the value measured with radiochromic film, in the posterior to anterior plane. In the lateral plane, Caregraph® uniformly underestimated the dose by an average of 67%. This means that with appropriate correction factors, Caregraph® could be used reliably as a real time indicator of PSD.

Verification of Caregraph® Peak Skin Dose Data Using Radiochromic Film

BY

LT MUHAMMED A. OZEROGLU

Thesis submitted to the Faculty of the Department of Preventive Medicine and Biometrics Graduate Program of the Uniformed Services University of the Health Sciences in partial fulfillment of the requirement for the Degree of Master of Sciences in Public Health, 2005

ACKNOWLEDGEMENT

I am grateful to the Department of Interventional Radiology at the National Naval Medical Center, especially Dr. Donald L. Miller, for inspiring this thesis and performing the experimental exposures.

I am grateful to the Ionizing Radiation Division of the National Institute of Standards, especially Mrs. Michelle O'Brien for providing her in-depth knowledge and guidance in the area of x-ray calibration.

I would like to thank all the members of my committee for their time and assistance in helping me complete this program. Each and every member went out of his way to make sure I had access to every possible resource.

TABLE OF CONTENTS

CHAPTER ONE: INTRODUCTION

Background and Significance……1

Statement of Problem……3

Research Goal……4

Research Question and Specific Aims……4

CHAPTER TWO: LITERATURE REVIEW

Fluoroscopically Guided Interventional Procedures……5

Peak Skin Dose……6

Determination of Peak Skin Dose……8

X-ray Film Dosimetry……9

CHAPTER THREE: MATERIALS AND METHODS

Alderson RANDO® Phantom……13

Gafchromic® XR Type R Film……14

Pixel Density Measurement:

Epson Flatbed Scanner……17

ImageJ® Software……17

NIST Calibration……18

Dose Determination……21

Caregraph® Data……24

Simulated Procedures……25

CHAPTER FOUR: RESULTS AND DATA ANALYSIS

Caregraph® Dose Results……28

NIST Calibrated Film Dose Results……29

Comparison and Analysis of Peak Skin Dose Data……30

CHAPTER FIVE: DISCUSSION AND CONCLUSIONS

Discussion……..31

Conclusions……32

APPENDIX A: LIMITATIONS AND FUTURE RESEARCH

Limitations……..34

Future Research……35

BIBLIOGRAPHY……...36

LIST OF TABLES

Table 1: Caregraph® Dose Results……28

Table 2: NIST Calibrated Film Dose Values……29

Table 3: Comparison of Caregraph® and NIST Calibrated Film PSD Values…30

LIST OF FIGURES

Figure 1: Alderson RANDO® Female Anthropomorphic Phantom……..13

Figure 2: Gafchromic® XR Type R Film Construction……14

Figure 3: Characteristic Absorption Spectrum of Gafchromic® Film……15

Figure 4: Energy Dependence of Gafchromic® XR Type R Film……..16

Figure 5: Sensitivity of Gafchromic® XR Type R Film……16

Figure 6: Sample Scan of Neuroembolization Study Film……..17

Figure 7: PSD Determination Using ImageJ® Software……18

Figure 8: NIST 300kV Tungsten X-ray Range……..19

Figure 9: NIST Wyckoff-Attix Free Air Chamber……..19

Figure 10: NIST In-Air Calibration Exposure……20

Figure 11: NIST Reproducibility Exposures……..21

Figure 12: Calibration Curve Given by MATLAB® ver 7.0.1……..22

Figure 13: Goodness of Fit Data for Calibration Curve……...23

Figure 14: Caregraph® Display for Simulated Neuroembolization Study…….25

Figure 15: Study Films on RANDO® for TIPS, UAE and Neroembolization…...26

Figure 16: Siemens Neurostar Interventional Fluoroscopy Unit Setup……26

Figure 17: Plot of Caregraph® PSD Data in PA and Lateral Plane vs Pixel Data in Neuroembolization Studies……33

CHAPTER ONE: INTRODUCTION

Background and Significance

Fluoroscopically guided medical procedures are an essential part of the practice of interventional radiology. In recent years, new procedures have been developed which are associated with higher radiation doses for imaging and guidance. Radiation dose to the skin in some of these procedures (e.g. cardiac electrophysiology studies, transjugular intrahepatic portosystemic shunts (TIPS), uterine artery embolization, neuroembolization procedures) has been high enough to cause deterministic skin injuries.[1-4] The formal radiological definition of absorbed dose is the energy absorbed in a unit mass of matter.[7-10] The threshold dose for deterministic skin injuries varies from 2 Gy for early transient erythema to 12 Gy for delayed necrosis.[7]

The Food and Drug Administration (FDA) has recommended that medical facilities record in the patient's record "an unambiguous identification of those areas of the patient's skin that received an absorbed dose that may approach or exceed the selected threshold". [11] Interventional procedures usually involve the x-ray beam moving over incongruous areas of the patient's body, sometimes in multiple planes, and persisting in various areas during the study as required by the interventionalist. Thus the dose delivered to a patient by an interventional procedure varies at different points on the patient's body. An accurate measurement or estimate of this dose distribution is technically difficult because the actual dose distribution is usually not known. Various simplifications have been made to estimate skin dose utilizing available technology.

Standard methods exist to estimate skin entrance dose.[12-18] In the United States, fluoroscopic time has been used for this purpose, but it underestimates the potential for skin injury because it does not reflect the dose rate and distribution of dose from digital angiography.[19] Dose-area-product measurements are used to estimate effective skin dose, but there can be a 30% - 40% error in the estimate.[16] In addition, this technique does not provide either peak skin dose data or mapping of skin dose. On-line patient exposure meters, such as integrated DAP meters, provide information on total skin dose, but also cannot provide data on peak skin dose or mapping of skin dose.[14]

Other methods are at least theoretically capable of determining peak skin dose. Thermoluminescent dosimeters (TLDs) can be taped to the patient's skin prior to the procedure. They can measure peak skin dose directly, only if they are placed at the site of maximal skin exposure. Unfortunately, the site of peak skin dose is difficult to locate in advance.[20] TLDs also require substantial physicist time and expertise for calibration and interpretation. Radiotherapy verification film or radiochromic dosimetry film can be used, but is cumbersome and requires physicist time for interpretation.[12,13] Both methods are labor-intensive, expensive, and intrusive. If a software method for dose estimation can be shown to be as effective and accurate at determining patient skin dose, time and expense can be saved. This would encourage routine collection and recording of these data. Currently, most institutions determine skin dose data only in special circumstances.[4,11,21]

Some fluoroscopic units used for interventional radiology and

interventional neuroradiology procedures are already equipped with an FDA-approved software program (Caregraph®, Siemens Medical Systems, Iselin NJ) that estimates peak skin dose in real time.[22,23] Neither patient preparation nor modification of the operator's technique is required. Peak skin dose and the spatial distribution of dose on the patient's skin are displayed on a computer monitor.[22-25] Caregraph® uses the fluoroscopic unit's gantry and table position information in real time to estimate the location of the skin surface. Using a computer model of the skin as an oblate cylinder with an average circumference of 100 cm, it calculates dose in air at the skin surface. Caregraph®'s advantage is that it can do this for sections of skin as small as 0.5 cm x 0.5 cm every 500 ms.[22-25] The disadvantage is that the oblate cylinder model is not accurate to the human body in all locations and, the algorithm omits the dose contribution from backscattered x-rays from the body.[23] Despite these drawbacks, Caregraph® is currently the best real-time indicator of the location and intensity of peak skin dose during interventional procedures. In order to utilize this tool, the accuracy of its estimation of peak skin dose is required.

Statement of the Problem

The high skin doses possible during interventional procedures can and have resulted in radiation induced skin injuries in patients.[1-4] Caregraph® software could assist physicians in preventing these injuries by providing real time dose and dose distribution during procedures. In cases where skin injuries are probable due to delivered dose, Caregraph® data can be used to document the

location and magnitude of the peak skin dose, for the treatment of injuries that could manifest in the future. In order to verify the peak skin dose data provided by Caregraph®, measurements were performed using radiochromic film calibrated at the National Institute of Standards and Technology (NIST).

Research Goal

The goal of this research was to determine if the skin dose data provided by Caregraph® software is accurate enough to predict and document peak skin doses in an effort to avert deterministic skin injury.

Research Question and Specific Aims

Research Question: Is the peak skin dose estimate provided by Caregraph® accurate and reliable enough to effectively predict peak skin doses delivered during fluoroscopically guided interventional procedures?

Specific Aims:

1. Calibrate Gafchromic® XR Type R film using the NIST standard M80 x-ray beam, including backscatter, from an Alderson RANDO® phantom.
2. Compare peak skin dose data provided by Siemens Caregraph® software with measured values from NIST-calibrated Gafchromic® film using standard statistical methods.

CHAPTER TWO: LITERATURE REVIEW

Fluoroscopically Guided Interventional Procedures

A fluoroscopically guided interventional procedure is classified as any surgical procedure where an instrument is inserted through a small opening in the body and guided in real time by a surgeon using a view of the anatomy provided by high power fluoroscopy.[26] In addition to fluoroscopy, several digital angiographic images can also be collected during a case to aid with diagnosis or consultation.[22,26]

Compared to the risks of invasive surgery, the risks of stochastic and deterministic injury to the skin during these procedures are very small.[21,22,26] Due to this and several other medical reasons, fluoroscopically guided interventional procedures are becoming more and more common.[22,26]

Most fluoroscopically guided interventional procedures have little risk of radiation injury to the skin. [21,22,26] Some common procedures, however, can produce doses high enough to cause skin injuries. These include (TIPS) creation, renal angioplasty, multiple hepatic/biliary procedures and neuroembolizations.[1-6,11,15-18,21-24,26] Doses in excess of 5 Gy have been recorded during some of these procedures. Injuries ranging from transient skin reddening or erythema to chronic ulceration and dermal necrosis have occurred.[1-6,11,19,22,24,26] The typical accepted threshold dose for transient erythema is estimated to be about 2 Gy.[7,11,25,26]

During interventional procedures, the highly collimated beam is usually moved around the patient as needed by the surgeon. This causes a distribution

of the dose over an area of the skin. Depending on the procedure and the specific anatomy of the patient, the beam can either overlap certain areas or stay in one area for a prolonged period of time.[22,26] This results in a high dose being delivered to a small portion of the skin. This incidence of peak skin dose is the vehicle of deterministic skin injury.[21,25]

Based on anecdotal reports of injuries, the FDA recommended in a 1994 public health advisory that dose data during certain high dose interventional procedures be collected and maintained.[11,21,26]

Peak Skin Dose (PSD)

The risk of deterministic skin injuries during fluoroscopically guided interventional procedures comes from radiation dose to the skin. The approximate threshold dose for early transient erythema is 2 Gy.[7,11,26] At approximately 7 Gy, permanent epilation occurs.[7] Delayed necrosis of the skin can occur within a year after exposure to approximately 12 Gy.[7] All of these thresholds can be higher or lower depending on age, patient sensitivity and area of skin exposed.[7,21,26] The threshold for deterministic injuries is dramatically reduced as the dose is concentrated in a smaller area of the skin.[8] The peak skin dose is the maximum dose delivered to a small area of the skin during an interventional procedure.[21,24-26]

There are four methods of estimating skin dose received during interventional procedures.[21,24,25] Cumulative fluoroscopy time is the most basic method and also the only one currently required by the FDA.[11,21,22,25] Dose Area Product

(DAP) is a more sophisticated method that takes an integral of dose across the entire x-ray beam.[21,22,24,25] Cumulative Dose (CD) is a measure of the total dose delivered during the procedure calculated at a reference point that is central to the axis of the beam and a fixed distance from the isocenter of the gantry.[21,22,24,25] Peak Skin Dose (PSD) is the highest dose delivered to any point on the skin during the procedure.[21,22,24-26]

Fluoroscopy time is the poorest indicator of dose because it does not take into consideration the dose rate, dose distribution or the dose delivered during angiographic imaging.[21,24,25] If careful notes of beam location and intensity and number of images taken during the procedure are available, fluoroscopy time can be used to make an order of magnitude estimate of dose.[22,24]

DAP is measured by placing a transmission full-field ionization chamber in the entire beam between the final collimators and the patient's skin.[22,24] The dose across this area is used to calculate the dose over the area of the skin using field size.[21,22,24] This gives the maximum amount of dose delivered during the procedure. The drawback of DAP is that it does not give an indication of dose distribution.[22,24] The same DAP value can be used to indicate a small amount of dose over a large area or a large dose over a small area.[22,24] This can either overestimate or underestimate the dose delivered to the skin.[21,22,24] DAP also excludes dose delivered by angiographic imaging during a procedure and, the dose contribution from backscattered radiation from the patient.[21,24]

CD is an approximation of the total radiation dose to the skin, summed over the entire body.[21,24] CD includes dose from angiographic images to give total

dose delivered.[21,24] It is measured at a reference point determined by fluoroscopic geometry along the central axis of the beam called the Interventional Reference Point (IRP).[21,24] Because this point is fixed at 15 cm from the isocenter of the geometry, depending on patient thickness, it can either be inside or outside the patient. Coupled with the omission of backscattered dose, this can cause calculations to either underestimate or overestimate dose.[21,22,24] CD, like DAP, does not indicate dose distribution across the patient's skin.[21,22,24]

PSD is calculated by using real time computer monitoring software, such as Caregraph®, to map the dose delivered to different areas of the skin during the procedure.[21,22,24] Based on patient information, the software estimates the point where the beam strikes the skin surface using gantry location and table height provided by the machine. This allows real time dose mapping to reveal the location on the skin that receives the highest dose. This makes PSD determination the best of the four methods considered to evaluate deterministic skin injury risk.

Determination of Peak Skin Dose

Risk of deterministic skin injury at a specific location on the skin is related directly to the dose delivered to that location.[21,22,24] Therefore, in order to determine risk of skin injury, the location on the patient's skin that receives the highest dose must be known. PSD is calculated by Caregraph® software using continuous feedback from the fluoroscopy machine and a computer model of the patient's skin.[22,23]

Interventional fluoroscopy machines have sensors that report the position of their various moving parts.[22,24,27] These include the table height, gantry location, tube location and image intensifier location. [22,24,27] Using this location data and dose data from a DAP meter, the software can calculate the intensity of the x-ray beam at any point in space. [22,24,27]

The Caregraph® software also needs to estimate the location of the skin surface. Anatomical information including height, weight and vertex of the head are entered into the software before the procedure. Using these values and a computer model of the patient that estimates an oblate cylinder, the location of the skin surface is estimated in real time as the beam is moved during the procedure.[22-24]

Once the location of the beam hitting the patient's skin is known, the dose in air delivered to that point is calculated from data provided by the DAP meter.[22-24] This data is plotted every 500 ms for areas of 0.5 cm by 0.5 cm.[22-24] This gives a real time image of the dose distribution and location of PSD on the skin. [22-24]

X-ray Film Dosimetry

While real time dose information from the fluoroscopy machine can be helpful in determining PSD, it is only an estimate due to several limitations. The computer model of the patient's skin is a simplified cylinder that does not precisely represent the exact location of the skin during a procedure. [22-24] Most importantly, the dose data provided by the DAP meter only includes dose in air at the skin surface.[21-24] This can underestimate dose by up to 40% depending on

the contribution of backscatter dose from the patient.[21,23,28]

As x-rays penetrate the skin and go through the patient to reach the image intensifier, a certain percentage of the x-rays are reflected back from the deeper tissues and through the skin delivering a second dose to the skin.[9] This backscatter contribution is a function of the density of the tissue under the skin, the patient thickness, the field size of the beam, the source to skin distance and the energy of the beam.[28,29]

The only way to accurately measure the total dose delivered to the skin is to use dosimetry that can be processed after the procedure.[22] Thermoluminescent dosimeters (TLDs) can give very accurate measurements of dose. However, these TLDs are very small. In order to capture the dose to the area of the skin that received the PSD, it would require a large array of TLDs that would be both cumbersome and difficult to process in a timely manner.[22] This is not a practical method for determining PSD.

Another method of dosimetry involves x-ray film. Once properly calibrated, film can be used as a very accurate measure of dose.[9] Because film can be used in large pieces, it can also give an integrated overview of the dose distribution across the skin, showing areas of peak skin dose (or hot spots) from overlap and persistence visibly.[22] Traditional diagnostic x-ray film is easily available and processed in any hospital. The drawback to using traditional diagnostic x-ray film for measuring dose during interventional procedures is its range and energy dependence.[9]

The x-ray beam in interventional fluoroscopy is in the diagnostic range of

energies from 60 kVp – 120 kVp.[22] The long exposure times and high dose rate associated with interventional procedures, however, produces doses that far exceed the range of diagnostic x-ray films. The film is saturated well before any dose determination is possible.[30] X-ray films used for dosimetry in radiation therapy have a much higher range suitable to measuring doses that can far exceed those seen in interventional fluoroscopy. However, these films are made for the high energy beams used in therapy, in the range of 6 MeV or higher.[31] When exposed to low energy x-rays, the energy dependence of the film causes it to over respond and saturate at relatively lower doses.[9] Test exposures performed at NIST using radiation therapy verification films resulted in all of the films being saturated at or about the 30 cGy level.

For this reason, radiochromic films have been developed that are designed for high doses at low diagnostic energies. These are ideal for use in interventional fluoroscopy dosimetry.[32] Radiochromic films use chemical radiation sensors that change color when exposed to the appropriate energy of ionizing radiation.[33] One of the many advantages of these films is that they are not sensitive to light, so they can be safely manipulated outside of a darkroom in normal lighting conditions. This eliminates the need to cut the film to the appropriate size in a darkroom.[33] They also require no chemical processing.[33] This eliminates the variability that can be introduced by chemical film processing due to chemistry and temperature.[9] The radiochromic film designed for dosimetry in interventional fluoroscopy is Gafchromic® XR Type R (International Specialty Products, Wayne NJ). This film has a wide dose response range (up to 15 Gy)

and comes in large 14” x 17” (35.6 cm x 43.2 cm) sheets that can easily cover the pertinent surface of the patient’s skin during interventional procedures.[32] The resulting dosimeter gives a directly visible distribution of the dose on the skin, in addition to an accurate and reliable measure of the dose at all locations including the PSD.[32]

CHAPTER THREE: MATERIALS AND METHODS

Alderson RANDO® Phantom

An Alderson RANDO® female anthropomorphic radiation therapy phantom (Figure 1) was used to simulate a human patient during the experimental exposures. The phantom is 155 cm (5 ft. 1 in.) tall and weighs 55 kg (110 lb).[34] It is transected horizontally into 2.5 cm thick slices.[34] The skeleton and soft tissues are made of highly detailed polymer moldings that reproduce the density and mass attenuation coefficients of the International Commission of Radiation Units and Measurement Report No. 44 (ICRU-44).[34] The lungs are molded from syntactic foam that has a specific gravity of 0.30 g/cc to match ICRU-44.[34]

Figure 1: Alderson RANDO® Female Anthropomorphic Phantom

Because the RANDO® phantom accurately represents average human dimensions, it made it possible to setup the Caregraph® software starting dimensions for a patient and perform the experimental studies over representative areas of anatomy. The anatomically accurate contours of the phantom allowed placement of the radiochromic film as close to the simulated skin surface as possible, in order to more accurately simulate the geometry of the

patient's skin during exposures.

The ICRU-44 equivalent density of the phantom allowed the automated exposure control systems on the interventional fluoroscopy units to behave just as they would if a human subject was on the gantry. The machine automatically adjusted kVp settings and filtration just as it would have as it traversed a human patient.

Most importantly, the phantom's ICRU-44 equivalent tissue density provided the backscatter component of the radiation dose to the radiochromic film as accurately as possible.

GAFCHROMIC® XR Type R Film

The dosimetry media used in this study was a radiochromic film, Gafchromic® XR Type R manufactured by the Advanced Materials Group of International Specialty Products Corporation. The film dimensions were 14" x 17" (35.6 cm x 43.2 cm) with a 15-micron active layer sandwiched between a 3.8-mils yellow transparent polyester layer and a 3.8-mils white opaque polyester layer (Figure 2).[33]

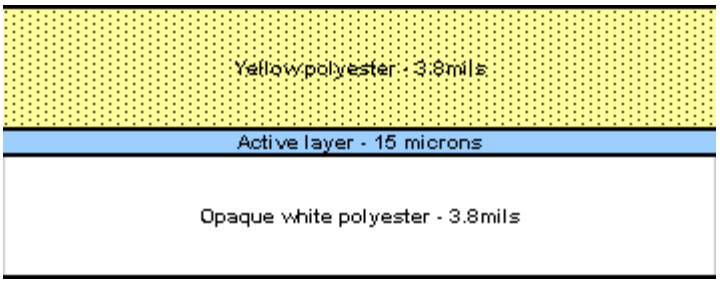

Figure 2: Gafchromic® XR Type R Film Construction

This construction is designed for reflection densitometry.[33] The film instantly changes color from orange to green as a function of exposure when exposed to ionizing radiation and requires no chemical processing.[33]

The active layer contains a proprietary microcrystalline radiation sensitive monomer dispersed in a gelatin matrix.[33] The radiation sensitive monomer is somewhat similar to stearic acid, which is a diacetylene. It is only radiation sensitive when in a crystalline state. When exposed to ionizing radiation, the active diacetylene polymerizes to form a polydiacetylene dye.[33] This dye has a major absorbance peak at 675 nm and a minor absorbance peak at 615 nm (Figure 3).[33]

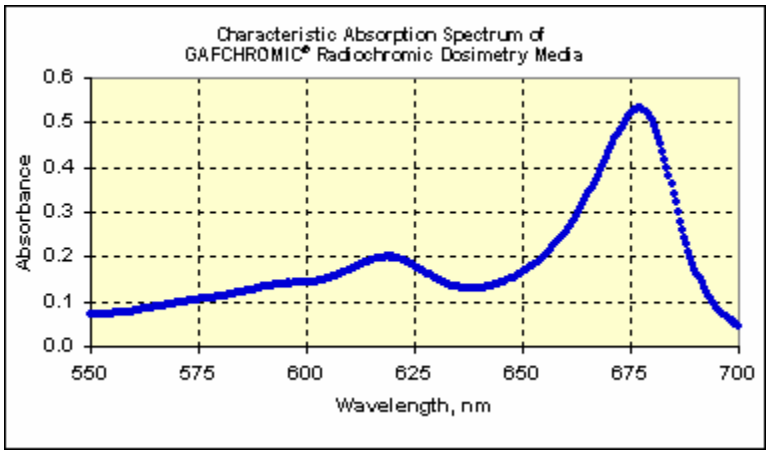

Figure 3: Characteristic Absorption Spectrum of Gafchromic® Film

Because only ionizing radiation causes the polymerization, the film is not sensitive to visible light and can be safely handled outside of a darkroom.[33]

The XR Type R version of the Gafchromic® film is designed for use in Fluoroscopically guided interventional procedures.[33] It is sensitive to x-ray energies between 60 kVp and 120kVp from 0.1 Gy to 15 Gy (Figures 4 and 5).[33]

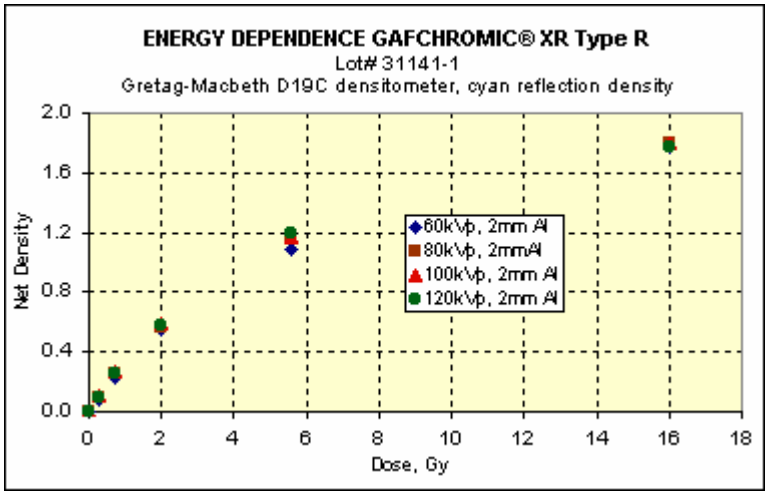

Figure 4: Energy Dependence of Gafchromic® XR Type R Film

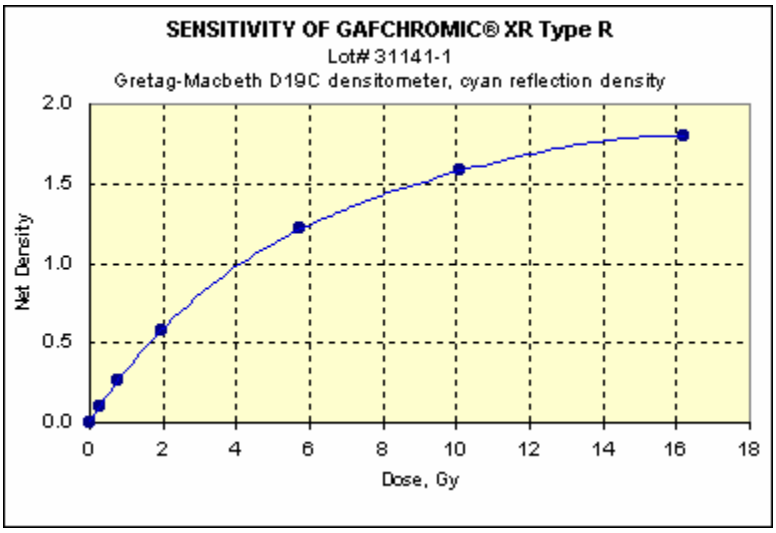

Figure 5: Sensitivity of Gafchromic® XR Type R Film

The manufacturer recommends calibrating films from only the same batch and allowing 24 hours for the radiochromic dye to stabilize before reading the film.[33,35]

The films were read after exposure by scanning them with a flatbed scanner, then analyzing the resulting scanned image's red color channel using pixel density measurement software.

Pixel Density Measurement:

Epson Flatbed Scanner

The manufacturer recommended using a flatbed scanner to read the Gafchromic® XR Type R film.[33] An Epson Perfection 4870 Photo scanner (Seiko Epson Corporation, Nagano, Japan) with 4800 x 9600 dpi resolution and 48-bit color depth was used to scan the films. Based on published studies, a black opaque background was placed behind each film to avoid any light transmission from behind the film.[35] The images were acquired using VueScan image scanning software (Hamrick Software, Phoenix, Arizona) at 300 dpi resolution (Figure 6).

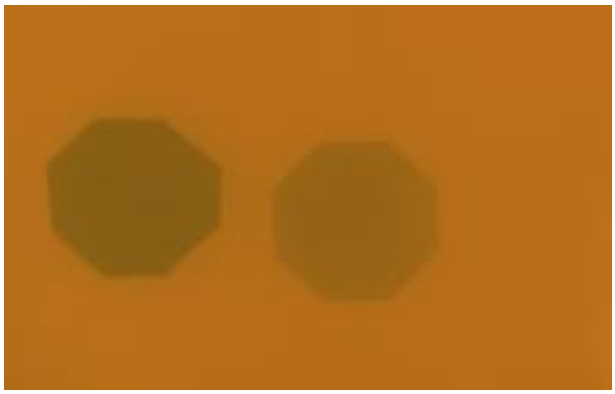

Figure 6: Sample Scan of Neuroembolization Study Film

ImageJ® Software

The scanned images were analyzed for pixel density using ImageJ® version 1.33u (National Institutes of Health, Bethesda, Maryland) image analysis software. The images were cropped to a region of interest that included the area that received exposure and then split into red, green and blue color channels. The red pixel density was recorded. In the case of calibration films, the average red pixel density and standard deviation over an area of 300 pixels by 240 pixels

was determined. In the case of study films, the darkest region of the film was cropped and the resulting histogram of red pixel density was used to find the minimum red pixel density value reported in an area greater than 500 pixels. This value was recorded as the highest dose (Figure 7).

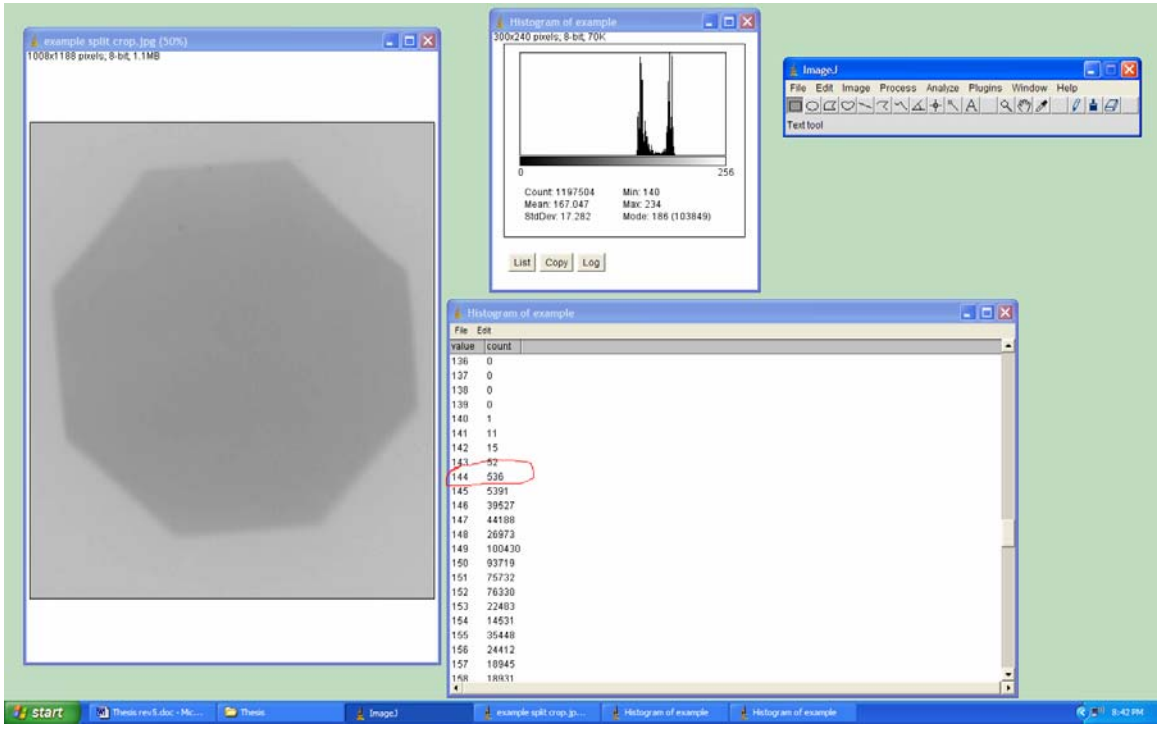

Figure 7: PSD Determination Using ImageJ® Software

NIST Calibration

In order to be used as an accurate dosimeter, x-ray film must be calibrated to the beam quality and range of the x-ray beam that it will measure. The beam quality of the interventional fluoroscopy units was measured with a kVp meter (Keithley 35050A , Keithley Instruments Inc., Cleveland, OH) during simulated procedures on the RANDO® phantom. The average beam quality was determined as 80 kVp. A NIST standard beam was selected that most closely

matched the beam quality of the interventional fluoroscopy units. The Gafchromic® XR Type R film was calibrated with the standard M80 beam of the 300 kV tungsten range at NIST (Figure 8).

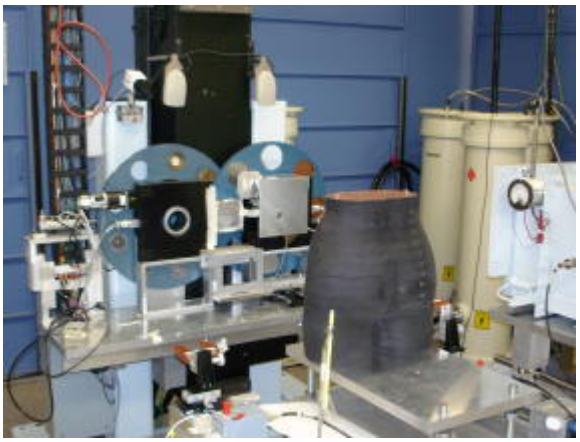

Figure 8: NIST 300kV Tungsten X-ray Range

The beam is 80 kVp with a half value layer of 2.97 mm Al.[36] The terminal field size was 21.3 cm in diameter at a source-to-target distance of one meter.[36] The M80 beam was characterized by the NIST calibration supervisor before each session using the Wyckoff-Attix free air chamber (Figure 9).[36]

Figure 9: NIST Wyckoff-Attix Free Air Chamber

Using the free air chamber, an air kerma rate and an exposure rate was determined for each session of exposures.

The film was cut into sections of 6” x 6” (15.24 cm x 15.24 cm). A calibration curve in air was constructed by making a series of exposures ranging from 5 to 130 cGy air kerma (Figure 10).

Figure 10: NIST In-Air Calibration Exposure

A second calibration curve that included backscatter dose was constructed by repeating the exposures with the film placed on the RANDO® phantom. Finally, reproducibility was investigated by repeating exposures at the same dose 3 times in the different areas of the RANDO® phantom corresponding to the study locations (Figures 11).

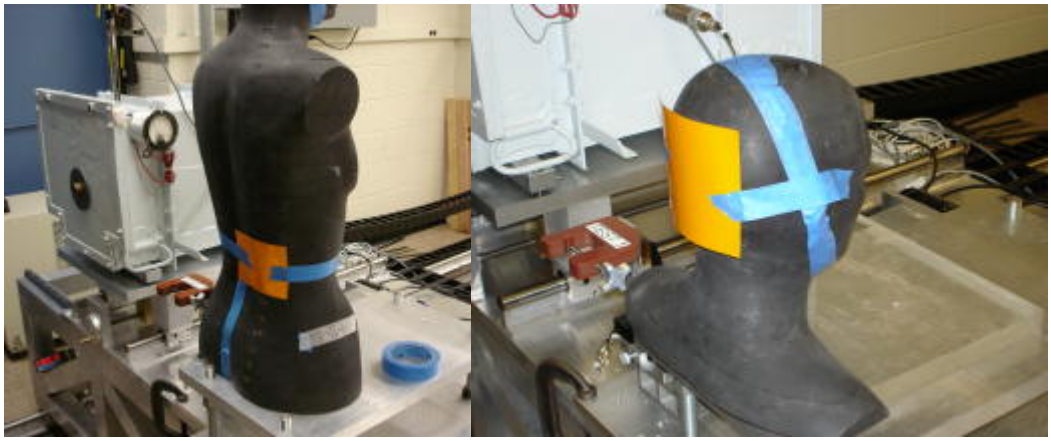

Figure 11: NIST Reproducibility Exposures

Dose Determination

The dose delivered to the film was calculated using the exposure rate in Roentgen per second (R/s) provided by the NIST calibration supervisor. For each exposure, the exposure rate was multiplied by the exposure time reading from the NIST exposure control computer.[36] The resulting exposure in roentgens was converted to delivered dose in rads using the below equation,[10]

$$rads = \frac{87.7}{100} \times \frac{\mu_m / \rho_m}{\mu_a / \rho_a} \times roentgens$$

where μ_m and μ_a are the mass attenuation coefficients for ICRU-44 soft tissue and air respectively[37] and ρ_m and ρ_a are the densities of ICRU-44 soft tissue and air.[37]

The delivered dose in rads was plotted vs pixel density using MATLAB® ver 7.0.1 (MATLAB®, MathWorks, Natick, Massachusetts). This plot for the in-air exposures was used as the calibration curve for all study films (Figures 12). The resulting curve had an R-square value of 0.997 (Figure 13).

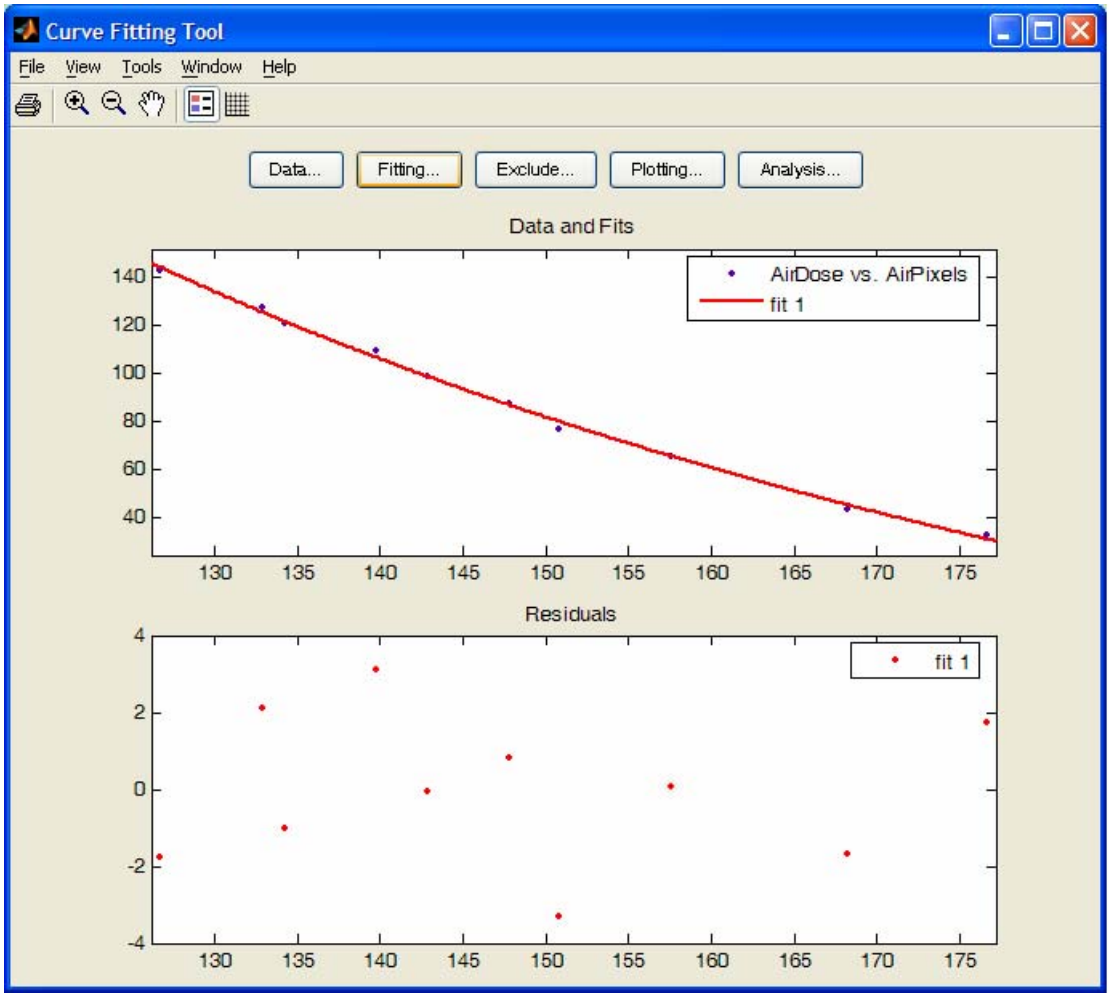

Figure 12: Calibration Curve Given by MATLAB® ver 7.0.1

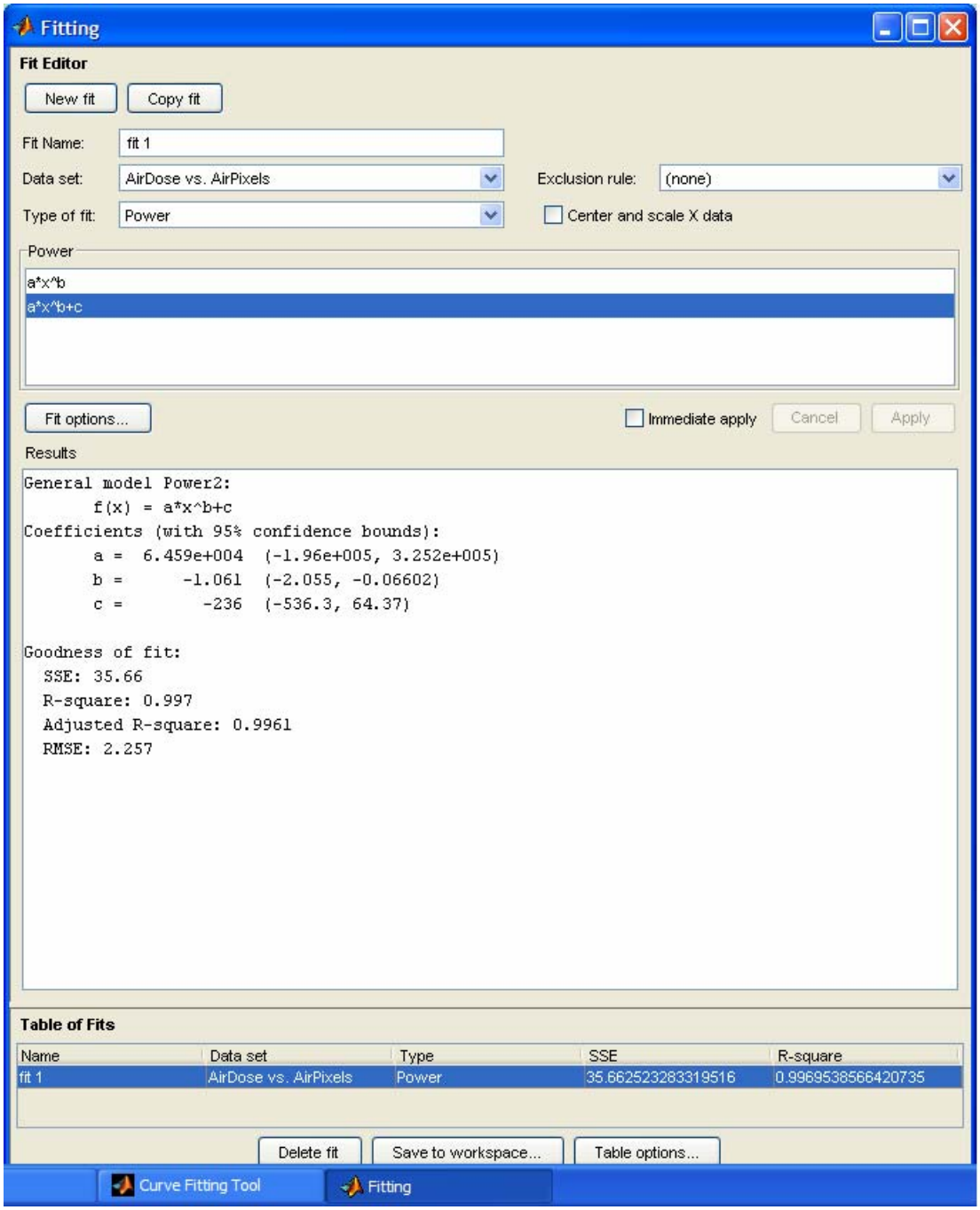

Figure 13: Goodness of Fit Data for Calibration Curve

The study exposures, with the film contoured on the RANDO® phantom, contained an inherent backscatter dose contribution from the phantom. This caused the films to be darker than the in-air calibration films at the same dose.

The dose due to backscatter was automatically included in the calculation when the study films were measured using the calibration curve made from in-air exposures. This eliminated error due to complicated mathematical modeling analysis of the backscatter calibration curve to the in air curve.

Caregraph® Data

As the interventional radiologist operates during a fluoroscopically guided procedure, Caregraph® generates a real time display of the dose as mapped to the patient's skin. As seen in Figure 14, Caregraph® gives several indicators of dose. The DAP is continuously updated as the exposed area increases and as the fluoro time increases. The area of the skin that has received 95% of the predetermined threshold dose of 1000 mGy is shown as the 95% Area Load. The PSD is also continuously updated to show the maximum dose delivered to any area of the patient's skin that is 0.5 cm by 0.5 cm. This value is displayed in both planes separately on the dose distribution map and as the highest value on the data table and is labeled as "max. Hot Spot".

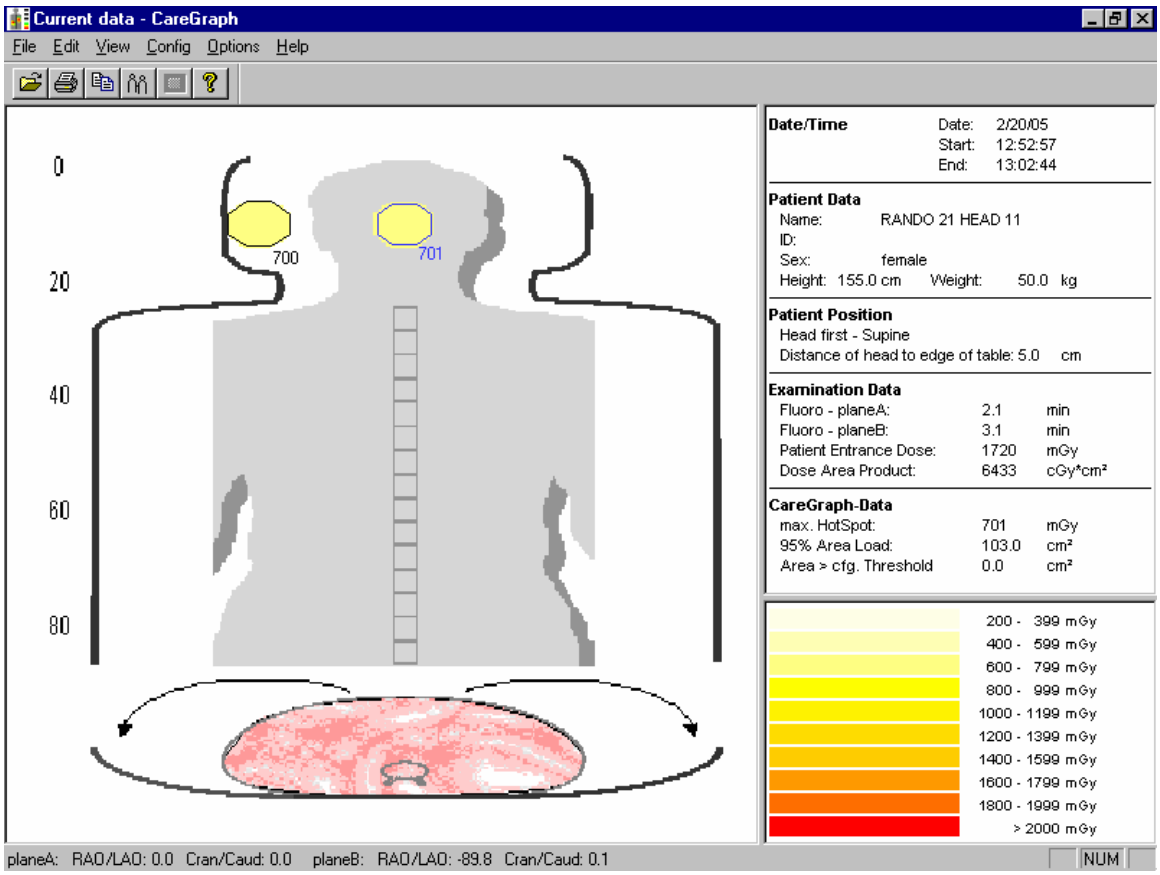

Figure 14: Caregraph® Display for Simulated Neuroembolization Study

Simulated Procedures

The interventional radiologist selected three of the most common high dose fluoroscopically guided procedures to simulate during the study. For each procedure, a piece of film that was big enough to capture the entire procedure was applied as close to the RANDO® phantom's surface as possible (Figure 15).

Figure 15: Study Films on RANDO® for TIPS, UAE and Neroembolization

The phantom's dimensions and weight were entered into Caregraph®. Fluoroscopy times and digital angiographic images that corresponded to actual patient studies were reproduced.

Five transjugular intrahepatic portosystemic shunts (TIPS) and five uterine artery embolizations (UAE) were simulated on the Siemens Multistar (Siemens Medical Systems, Iselin NJ) unit at National Naval Medical Center (NNMC), Bethesda, Maryland. Twelve neuroembolization procedures were simulated on the Siemens Neurostar (Siemens Medical Systems, Iselin NJ) unit in the interventional suite at NNMC. This unit has a fluoroscopy tube and an image intensifier in both the lateral plane and the anterior/posterior plane (Figure 16).

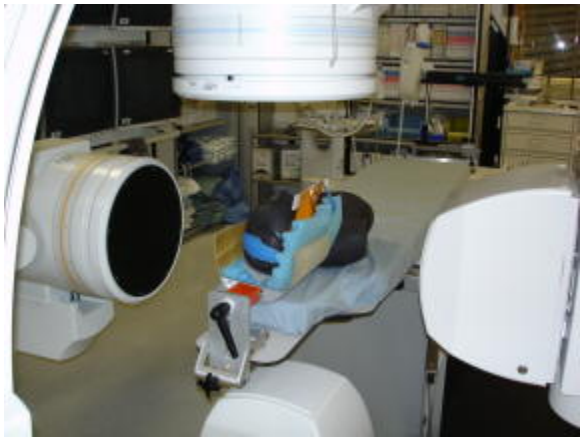

Figure 16: Siemens Neurostar Interventional Fluoroscopy Unit Setup

Ten of the neuroembolizations were simulated so that the “max Hot Spot” indicated by Caregraph® were equal in both planes.

One of the neuroembolization simulations was aborted early because the unit’s automatic protection system activated when the heat unit threshold on the tube was reached and the Caregraph® software reset the display data. One of the neuroembolization simulations was done with both planes simultaneously resulting in an uneven dose delivered to each plane.

CHAPTER FOUR: RESULTS AND DATA ANALYSIS

Caregraph® Dose Results

The dose data collected from the final Caregraph® display for each of the studies is presented in Table 1.

Study	PSD (cGy)	Cumulative dose (mGy)	DAP (cGy/cm$^{2)}$
TIPS 01	100.0	1459	9653
TIPS 02	120.0	1654	9860
TIPS 03	151.6	1612	11561
TIPS 04	150.0	1321	12183
TIPS 05	150.0	1349	8348
UAE 01	90.1	1363	12458
UAE 02	120.0	1577	13226
UAE 03	120.0	1534	10828
UAE 04	120.0	1464	10884
UAE 05	120.0	1467	7734
Neuro PA 1	101.2	1093	4490
Neuro PA 2	100.2	1002	3903
Neuro PA 3	80.3	902	3525
Neuro PA 4	90.0	1012	3952
Neuro PA 5	70.1	794	3082
Neuro PA 6	70.0	755	2980
Neuro PA 7	70.1	754	2980
Neuro PA 8	70.0	754	2979
Neuro PA 9	70.1	754	2980
Neuro PA 10	82.5	879	3507
Neuro PA 11	70.1	755	2981
Neuro PA 12	120.1	1274	5100
Neuro LAT 1	80.0	1116	4563
Neuro LAT 3	80.0	1047	3710
Neuro LAT 4	90.0	1178	4174
Neuro LAT 5	70.0	919	3242
Neuro LAT 6	70.0	970	3455
Neuro LAT 7	70.0	967	3451
Neuro LAT 8	70.0	968	3455
Neuro LAT 9	70.1	969	3457
Neuro LAT 10	75.0	1014	3686
Neuro LAT 11	70.0	966	3452
Neuro LAT 12	120.0	1631	5903

Table 1: Caregraph® Dose Results

NIST Calibrated Film Dose Results

The study films for each simulated procedure were scanned and the resulting pixel values for the maximum hot spot were converted to PSD with the calibration curve. The dose data for each study is presented in Table 2.

Study	Red Pixel Value	Skin Dose (cGy)
TIPS 01	147	88.7
TIPS 02	140	106.0
TIPS 03	130	134.0
TIPS 04	136	116.6
TIPS 05	135	119.4
UAE 01	143	98.4
UAE 02	130	134.0
UAE 03	132	128.0
UAE 04	134	122.2
UAE 05	137	113.9
Neuro PA 1	140	106.0
Neuro PA 2	144	95.9
Neuro PA 3	149	84.1
Neuro PA 4	146	91.1
Neuro PA 5	152	77.4
Neuro PA 6	154	73.1
Neuro PA 7	153	75.3
Neuro PA 8	154	73.1
Neuro PA 9	154	73.1
Neuro PA 10	150	81.9
Neuro PA 11	154	73.1
Neuro PA 12	138	111.2
Neuro LAT 1	128	140.1
Neuro LAT 3	132	128.0
Neuro LAT 4	128	140.1
Neuro LAT 5	137	113.9
Neuro LAT 6	134	122.2
Neuro LAT 7	133	125.1
Neuro LAT 8	134	122.2
Neuro LAT 9	136	116.7
Neuro LAT 10	134	122.2
Neuro LAT 11	134	122.2
Neuro LAT 12	115	185.3

Table 2: NIST Calibrated Film Dose Values

Comparison and Analysis of Peak Skin Dose Data

The peak skin dose values for each study, as given by Caregraph® and by the NIST calibrated film, were compared. The average percent difference and standard deviation for each type of study is listed in Table 3.

Study	CG PSD (cGy)	Film PSD (cGy)	Percent Difference CG/Film
TIPS 01	100.0	88.7	11.3
TIPS 02	120.0	106.0	11.7
TIPS 03	151.6	134.0	11.6
TIPS 04	150.0	116.6	22.2
TIPS 05	150.0	119.4	20.4
		Mean	**15.4**
		Std Dev	4.8
UAE 01	90.1	98.4	-9.2
UAE 02	120.0	134.0	-11.7
UAE 03	120.0	128.0	-6.7
UAE 04	120.0	122.2	-1.8
UAE 05	120.0	113.9	5.1
		Mean	**-4.9**
		Std Dev	5.9
Neuro PA 1	101.2	106.0	-4.7
Neuro PA 2	100.2	95.9	4.3
Neuro PA 3	80.3	84.1	-4.7
Neuro PA 4	90.0	91.1	-1.2
Neuro PA 5	70.1	77.4	-10.4
Neuro PA 6	70.0	73.1	-4.4
Neuro PA 7	70.1	75.3	-7.4
Neuro PA 8	70.0	73.1	-4.4
Neuro PA 9	70.1	73.1	-4.3
Neuro PA 10	82.5	81.9	0.7
Neuro PA 11	70.1	73.1	-4.3
Neuro PA 12	120.1	111.2	7.4
		Mean	**-2.8**
		Std Dev	4.9
Neuro LAT 1	80.0	140.1	-75.1
Neuro LAT 3	80.0	128.0	-60.0
Neuro LAT 4	90.0	140.1	-55.7
Neuro LAT 5	70.0	113.9	-62.7
Neuro LAT 6	70.0	122.2	-74.6
Neuro LAT 7	70.0	125.1	-78.7
Neuro LAT 8	70.0	122.2	-74.6
Neuro LAT 9	70.1	116.7	-66.5
Neuro LAT 10	75.0	122.2	-62.9
Neuro LAT 11	70.0	122.2	-74.6
Neuro LAT 12	120.0	185.3	-54.4
		Mean	**-67.3**
		Std Dev	8.6

Table 3: Comparison of Caregraph® and NIST Calibrated Film PSD Values

CHAPTER FIVE: DISCUSSION AND CONCLUSIONS

Discussion

The goal of this study was to compare the PSD estimated by Caregraph® to direct dosimetry measurements via film. The film measurements included backscatter to give the most accurate actual peak skin dose values that were possible. The expected results were that Caregraph® would underestimate the PSD because it did not include the published 38% backscatter contribution[28] in its algorithm.

The data showed that in the case of single plane PA measurements, in TIPS and UAE procedures, Caregraph® PSD values were relatively close to actual PSD via film that included backscatter dose. In some cases, Caregraph® estimated conservatively and thus was protective. In the mutliplane neuroembolization procedures, the PA plane results were again relatively close to the direct measurements. In the lateral plane, however, Caregraph® not only underestimated the dose by an average of 67%, it also disagreed with its own displayed value for both planes. In each instance where Caregraph® reported equal PSD in both planes, it uniformly underestimated the dose in the lateral plane by as much as 78%.

Because Caregraph® uses the same algorithm to calculate dose in both planes, the difference cannot be attributed to the omission of backscatter dose. A more logical explanation is that the attenuation of the gantry table and table pad in the PA plane reduces the delivered PSD in that plane as compared to the lack of attenuation in the lateral plane[38].

The qualitative dose distribution as displayed by Caregraph® matched that of the film in every instance. The only discrepancy was the obvious difference in darkness in the lateral and PA planes on the film that Caregraph® called equal.

Conclusions

Even without considering backscatter dose in its algorithm, Caregraph® can estimate actual PSD to within an average of 15% in the PA plane. The underestimation in the lateral plane is fairly uniform and therefore, can likely be compensated for in the algorithm with a correction factor. A plot of the PSD data provided by Caregraph® in the PA plane and the lateral plane vs. the pixel data of the neuroembolization studies (Figure 17) shows that a correction factor could compensate for the underestimation in the lateral plane. With further research leading to an eventual adjustment of the dose algorithm, Caregraph® has the potential to be a very accurate real time dosimetry tool.

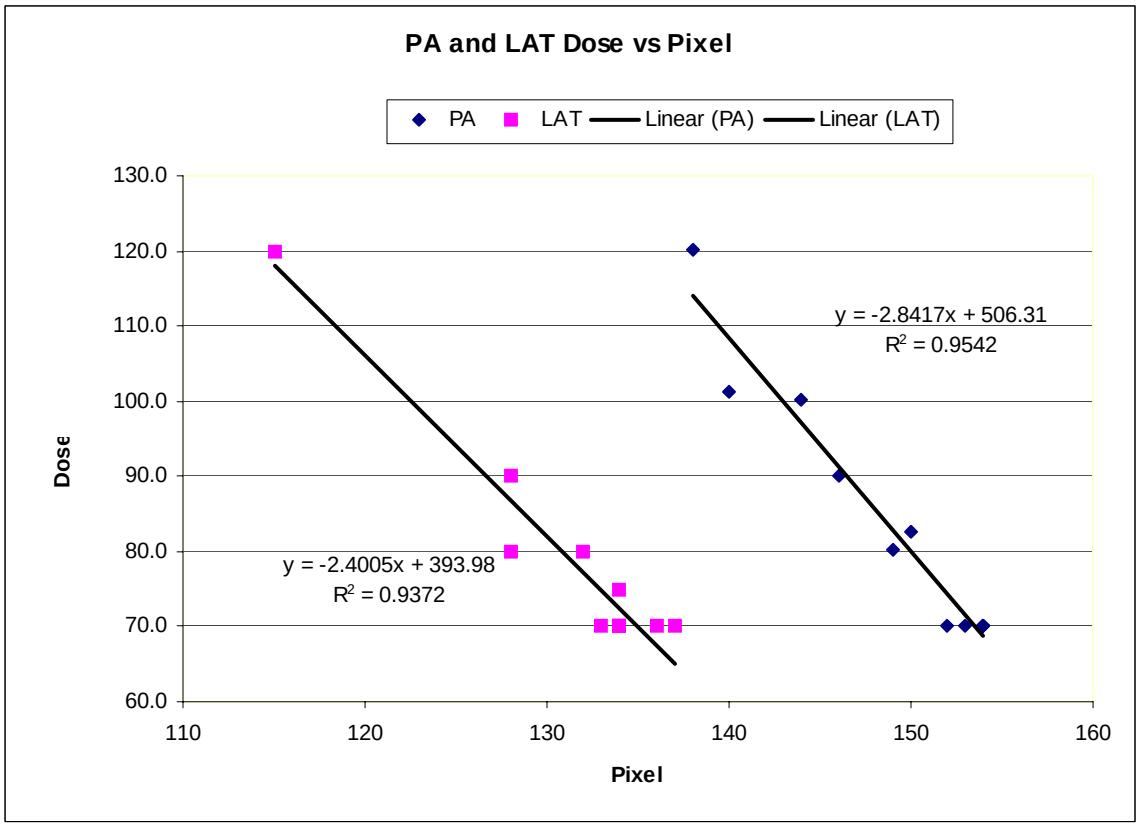

Figure 17: Plot of Caregraph® PSD Data in PA and Lateral Plane vs Pixel Data in Neuroembolization Studies

If the interventionalist can grow to rely on Caregraph® data during a study, future incidents of overexposure could be avoided or mitigated. Further accuracy in dose calculation combined with an already accurate dose distribution, could provide for a reliable patient record of dose after each procedure.

APPENDIX A: LIMITATIONS AND FUTURE RESEARCH

Limitations

The accuracy of the dosimetry used in this study was limited by several factors. The interventional fluoroscopy units continually changed kVp and filtration during the study depending on the density of the phantom in the beam. NIST had only one beam quality that would match the average kVp and filtration of the machines at NNMC. Also, the source to target distance of the NIST beam was constant at one meter. The source to target distance of the interventional units changed according to the study being performed. Both of these fluctuating values resulted in a fluctuating backscatter value, although this value did not change enough to make the measurements inaccurate.

The exposures at NIST were very time consuming. Some of the higher dose exposures were up to 40 min in length. Due to scheduling limitations for use of the calibration facility at NIST, a highly defined calibration curve for backscatter and air could not be created. If this were possible, a more accurate mathematical calculation of the backscatter factor could have been performed by using Monte Carlo modeling[29] on the two curves to determine an accurate backscatter factor.

The interventional suites at NNMC were very busy, as was the interventional radiologist who performed the simulated studies. With additional time for data collection with the RANDO® phantom, more statistical power could have been achieved by performing more studies.

Future Research

The results of this study show that Caregraph® can report PSD accurately with some modifications to the dose algorithm. Future studies should include:

1. More varied interventional procedures besides the three simulated here, in order to add further statistical power to the results.

2. Various makes and models of interventional fluoroscopy machines at various facilities should be evaluated to gain even more statistical power and to help eliminate the possibility of variation due to mechanical error.

3. Further studies using the Gafchromic® film and the RANDO® phantom should be done at varying energies in order to better characterize the backscatter factor using Monte Carlo modeling.

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